

DOCKET NO.: SNL-0004

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **West, *et al.***

Confirmation No.: **4414**

Serial No.: **10/701,097**

Group Art Unit: **1744**

Filing Date: **November 4, 2003**

Examiner: **Nathan Bowers**

For: **Microfluidic Integrated Microarrays for Biological Detection**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request review of the final rejection in the above-identified application.

No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s). No more than five (5) pages of remarks are provided. The following complies with the submission requirements of the Pre-Appeal Brief Request for Review.

/Aaron B. Rabinowitz/

Date: November 20, 2008

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REMARKS – REASON FOR REVIEW

Claims 1-114 of the present application stand finally rejected as allegedly obvious over certain prior art combinations. Applicants respectfully submit that the rejections should be reconsidered and withdrawn. First, the Examiner's proposed combination of references ignores the fact that the cited references teach away from their combination and away from the claimed invention, and the MPEP expressly forbids combining references that teach away from their combination. Second, even if the Examiner had established a *prima facie* case of obviousness, Applicants' evidence of superior results over the prior art and over existing alternative products overcomes that *prima facie* case under the standards set forth in the MPEP.

I. The MPEP Forbids The Examiner's Proposed Combination Of References That Teach Away From Their Combination And From The Claimed Invention

The final rejection of Applicants' claims is improper because the Examiner combined references despite the fact that the references teach away from their combination and from the claimed invention. This is flatly contrary to the clear guidance set forth in the MPEP and accordingly cannot support a *prima facie* case of obviousness.

Applicants' claim 1 recites, *inter alia*, "[a] microarray situated within at least one microchannel, the microchannel being characterized as having depth in the range of from about 1 micron to less than 10 microns." The Examiner based his rejection of this claim on the combination of the Mathies (US 2004/0209354), McNeely (US 2004/0037739), and Quake (US 6,833,242) references (Office Action at 3).

As the Examiner candidly acknowledged, however, "[t]he combination of Mathies and McNeely stills [sic] fails to disclose Applicant's claimed invention because neither reference teaches the use of microchannels having depths in the range of 1 to 10 microns" (Office Action at 3). To address Applicants' limitation regarding microchannel depth, the Examiner relied on Quake for that reference's mention of microchannels having a diameter of 2 to 5 microns. This reliance, however, is improper.

The Examiner's combination of references is improper because he ignored the references' own teachings and the clear guidance set forth in the MPEP. The McNeely reference states that the array-containing channels of that invention *must be* "**at least about 15 μ m** [microns]" in depth (*see* McNeely reference at [0084]). That statement in McNeely first teaches away from Applicants' claim 1 element of microchannels from **about 1 to about**

10 microns, which teaching away highlights that one of ordinary skill would *not* have relied upon the McNeely reference to arrive at Applicants' invention. *See* MPEP § 2145.X.D.1 (prior art reference that teaches away from claimed invention is significant factor to be considered in obviousness analysis).

Second, the fact that McNeely teaches away from channels less than 15 microns in depth makes clear that McNeely (channels must be **at least 15 microns** in depth) cannot be combined with Quake (channels **2-5 microns** in depth). The MPEP is clear that such a combination of references is impermissible: "[i]t is improper to combine references where the references teach away from their combination." MPEP § 2145.X.D.2 (citing *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983)). That is precisely the situation present in this case: while McNeely cautions against using channels **less than 15 microns** in depth, the Examiner nonetheless proposes combining McNeely with Quake, which describes channels **only 2-5 microns** in diameter. Because the references teach away from their combination, the McNeely-Quake-Mathies combination is improper under the MPEP and as a matter of Federal Circuit law, and, accordingly, cannot support the proposed obviousness rejection. MPEP § 2145.X.D.2.

Conceding that the McNeely reference teaches away from the claimed invention, the Examiner sought to sidestep the MPEP's clear prohibition on combining references that teach away from their combination by stating that "McNeely is not relied upon for teachings regarding channel dimension, but is merely cited for motivation regarding the use of microarrays during detection" (Office Action at 21). But the MPEP does *not* permit an Examiner to rely on only those parts of a reference he believes are most helpful to his position. Instead, an Examiner must address ***all*** parts of a prior reference and may not selectively apply only ***some*** parts of the reference; "[a] prior art reference must be considered in its entirety, *i.e.*, **as a whole**, including portions that would lead away from the claimed invention." MPEP § 2143.02.VI. By ignoring the fact that McNeely teaches away from both the claimed invention and from combination with Quake and by failing to explain why one of ordinary skill would ignore the teaching away contained in the McNeely reference, the Examiner failed to follow the procedure set forth in MPEP § 2143.02.VI. The Examiner's justification for his combination is thus based on no more than a hindsight rationale that selectively relies on only particular aspects of the cited references to arrive at the claimed invention and does not explain why one of ordinary skill would ever ignore the references'

teaching away from their combination. While the Examiner speculates at page 21 of the Office Action that “[i]t is well within the purview of one of ordinary skill in the art to weigh” the advantages the channels disclosed by Quake against the disadvantages of the channels described by McNeely, the Examiner’s suggestion cannot be reconciled with MPEP § 2145.X.D and the Federal Circuit’s *In re Grasselli* decision, both of which authorities make clear that “it is improper to combine references where the references teach away from their combination.”

Accordingly, because the Examiner combined McNeely and Quake without addressing the fact that McNeely teaches away both from combination with Quake and from the claimed invention, the McNeely-Quake-Mathies is improper under the MPEP and can not support a *prima facie* case of obviousness.

II. Applicants Provided Sufficient Evidence of Secondary Considerations To Rebut a *Prima Facie* Case of Obviousness

Even if the Examiner’s proposed combination of references were proper and could support a *prima facie* case of obviousness, Applicants submitted sufficient evidence of secondary considerations to overcome that *prima facie* case of obviousness. More specifically, in the declaration submitted on March 25, 2008, Dr. Jason A.A. West, a co-inventor of the present invention, stated that the claimed invention “achieves results that are unexpectedly superior to those of alternative devices in the field,” and Applicants supplied evidence – attached to the declaration – of the claimed invention’s unexpected superiority over existing devices and over the prior art. *See* MPEP § 2145 (*prima facie* case may be rebutted by evidence of claimed invention’s superior performance).

Regarding the claimed invention’s superiority over the cited prior art, the Examiner stated during the telephonic interview held on November 19, 2008 that a comparison between the claimed invention and the cited prior art would be useful in highlighting the claimed invention’s superior performance. Such a comparison is easily made and underscores the claimed invention’s superior performance.

The McNeely reference states that performing an analysis based on hybridization of probes to the microarrays disclosed in that reference includes, *inter alia*, an incubation period to allow the probes to hybridize to the array that is “typically performed **overnight**” (McNeely at [0153], emphasis added). By contrast, Exhibit B attached to Dr. West’s March 25, 2008 affidavit shows that the claimed invention achieves probe hybridization and detection in only about **5 minutes**. Assuming an 8-hour overnight incubation period, the

claimed invention thus represents a **96-fold improvement** over the prior art. This quantum of improvement is clear evidence of the claimed invention's nonobviousness, and is sufficient to overcome a *prima facie* case of obviousness. See MPEP § 2144.VII (**7-fold** improvement over the prior art rebutted *prima facie* case of obviousness).

The claimed invention is similarly superior to existing alternative products. As shown in Exhibit B to Dr. West's March 25, 2008 declaration, existing products require **14 hours** to produce the results the claimed invention achieves in only **5 minutes**. This 168-fold improvement again demonstrates the superiority of the claimed invention and is sufficient to overcome a *prima facie* case of obviousness.

Page 5 of Exhibit C attached to Dr. West's declaration likewise establishes that devices according to the claimed invention are capable of performing probe hybridization and detection in only several minutes, and also notes (at page 1 of that Exhibit) that the "major drawbacks" to existing hybridization-based assays are the long sample processing time and the extended time requirement for probes to hybridize to target DNA on a slide surface. Thus, Applicants' submissions clearly establish the secondary considerations of long-felt need in the art and the superiority of the claimed invention over existing devices and techniques. Accordingly, Applicants submit that the proffered evidence of secondary considerations establishes the non-obviousness of the claimed invention and that the Examiner did not properly consider such evidence. MPEP § 2145.

* * *

For all of the foregoing reasons, Applicants submit that the pending rejections should be reconsidered and withdrawn. First, the Examiner's proposed combination of references is improper because the cited references teach away from their combination and teach away from the claimed invention. Second, Applicants have provided evidence that the claimed invention exhibits performance that is significantly improved over the cited prior art and over existing alternative products.

Accordingly, Applicants submit that all pending claims are in condition for allowance and earnestly solicit the Review Panel to allow the application on the existing claims. Should any member of the Review Panel desire any additional information, they are invited to call the undersigned attorney at 215-568-3100.

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Respectfully submitted,

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